## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/21/09 has been entered.

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16 and 26-31 are drawn to a transdermal therapeutic system (TTS), classified in class 424, subclass 449.

II. Claims 18 and 24 are drawn to a method for preparing a TTS, classified in class 424, subclass 449.

III. Claims 20-23 and 25 are drawn to a method for preparing a TTS, classified in class 424, subclass 449.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the TTS of Group I can be made using different process. This is evident by the present claims. For example, the process of claim 18 is different from the process of claim 20, which does not require the step for pre-melting the components of the cement matrix.

Inventions II and III are directed to related process. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different mode of operation. As discussed above, the process of Group II does not require the step for pre-melting the components of the cement matrix. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species:

1) *Softener*: a) organic wax, b) ceresine, or c) ozokerite;

2) *Internal-phase component*: a) hydrophilic and amphiphilic polymers, b) hydrophilic and amphiphilic copolymers, c) condensates of glycerin and fatty acids, d) condensates of glycerin and polyols, e) polysaccharides, f) substituted polysaccharides, g) polyethylene oxides, h) polyvinyl acetates, i) polyvinyl pyrrolidones, j) copolymers of polyvinyl pyrrolidone and polyvinyl acetate, k) polyethylene glycol, l) polypropylene glycol, m) copolymers of ethylene and vinyl acetate, n) glycerin-fatty acid esters, or o) mixtures of polyvinyl alcohol with glycerin;

3) *Hot-meltable adhesive* is: a) EVA adhesive, b) SXS adhesive, or c) mixture of amine resistant silicone adhesive and softener; and

4) *Dopamine-metabolism disorder*: Parkinson's disease, or b) restless leg syndrome.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at

the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

A telephone call was made to Leanne M. Rakers on 12/07/09 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 18 and 20-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-59 of copending Application No. 10/523908 ('908). Although the conflicting claims are not identical, they are not patentably distinct from each other because application '908 claimed a transdermal therapeutic system (TTS) comprising a drug-containing hot-melt adhesive matrix produced by metering the drug into the solvent-free melt of the adhesive matrix at a temperature of 102°C-160°C. The TTS further comprises a drug and a softener (claims 28 and 31). Hot-melt adhesive includes amine-resistant silicone (claim 31). Softeners are found in claims 32 and 33. Drug include Rotigotine is found in claims 28, 29 and 42-44. Amount of drug is found in claims 34-36. Drug present in

form of a base is found in claim 37. Release profile is found in claims 46-48. Accordingly, the present claims are anticipated by the claims of the '908 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

Claims 1-16, 18 and 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 5,807,570, in view of Schollmayer US 2004/0048779 A1 and Noel. US Re. 36,754

Chen teaches a TTS comprising a backing layer, and an adhesive polymeric matrix which contains combination of a permeation enhancer and at least about 30% ropinirole or an analog thereof as an active agent (abstract; column 3, lines 1-37; column 4, lines 25-37; and column 6, lines 36-46). Permeation enhancer includes polyethylene glycol, propylene glycol, alcohol, and the like (column 7, lines 24-39). Active agent can be administered in the form of a base or pharmaceutically acceptable salt (column 7, lines 6-10). The polymeric matrix further comprises pressure sensitive adhesive polymer including silicone (column 8, lines 48-67).

Chen does not expressly teach the claimed active agent.

Schollmayer teaches a TTS comprising rotigotine for the treatment of restless leg syndrome (abstract). Schollmayer also disclose that the use of rotigotine for the treatment of Parkinson's disease is known in the art (paragraph 0016). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen to

include rotigotine as an active agent in view of the teaching of Schollmayer, because Schollmayer teaches that with rotigotine as the active substance it is only required very small doses compared to conventional monotherapies for the same treatment (paragraph 0012), because Schollmayer teaches ropinirol lead to side effects such as nausea, vomiting, dizziness, hypotension, constipation or insomnia, while rotigotine overcomes these drawback (paragraphs 0007-0011), and because Chen teaches the desirability to obtain a TTS useful for the treatment of Parkinson's disease.

Chen is silent with respect to the teaching of hot-melt process. Chen further does not teach the matrix system that comprises organic wax.

Noel teaches a hot-melt silicone-base TTS comprising silicone sensitive adhesive, and organic waxes having melting point between 30-150°C (abstract). Organic waxes include vegetable waxes, animal waxes, mineral waxes such as ozokerite, and mixtures thereof in an amount of from about 1 to about 25% (column 5, lines 1-11; and claim 17). Silicone sensitive adhesive is present in an amount from about 99-85% (column 8, lines 41-44). Noel further teaches the hot-melt silicone-base TTS is free of solvent (column 2, lines 66-67). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen using the hot-melt silicone-base TTS in view of the teaching of Noel to obtain the claimed invention. This is because Noel teaches a transdermal system that is highly efficacious, because Noel teaches using organic waxes to decrease viscosity and improve coatability which do not require the present of solvents (column 1, lines 66 through column 2, lines 1-3), because Noel teaches using organic waxes over the use of solvents to avoid: 1) removal and

containment of solvents, 2) special precautions to avoid fires, and 3) cost effectiveness (ID), because Chen teaches a TTS that comprises silicone and waxes as carriers (column 6, lines 25-27), and because Chen teaches the desirability to obtain a TTS that improved patient compliance and with less side effects (column 2, lines 51-60).

Claims 18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 5,807,570, in view of Schollmayer US 2004/0048779 A1, and Noel. US Re. 36,754, and Venkatraman et al. US 2005/0048104 A1.

Chen is relied upon for the reason stated above. Chen does not teach melting the active agent at the claimed temperature.

Venkatraman teaches a process for preparing a transdermal drug delivery system comprising melt-mixing drug such as fentanyl, into a polymer at a temperature of about 150°C (abstract; and claim 34). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation modify the TTS of Chen using the hot melt process in view of the teachings of Venkatraman. This is because Venkatraman teaches a hot melt process that protect active agent from degradation.

***Response to Arguments***

Applicant's arguments filed 09/21/09 have been fully considered but they are not persuasive.

Applicant states that Applicant may elect to argue to overcome the provisional obviousness-type double patenting rejection or to provide a terminal disclaimer (to the

extent necessary) once the present claims have been found to be otherwise allowable and/or once the co-pending application issues as a patent.

Accordingly, the rejection is maintained.

Applicant argues that all the features of Claim 1 must be considered against the combination of Chen, Metman, and Loper. In particular, the transdermal therapeutic system (TTS) of Claim 1 is formed using a process that imparts a structure unattainable by the cited references: "the cement matrix comprises a hot-meltable adhesive in which the active substance is dispersed and melted using a hot-melt process," the active substance being rotigotine. As claimed, the rotigotine is dispersed and melted, whereas nowhere in the combination of Chen, Metman, and Loper is there any disclosure or suggestion with respect to dispersing and melting an active substance. Structure implied by processing should be considered when assessing the patentability of product-by-process claims over the prior art where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero,* 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.). In the present case, a "cement matrix compris[ing] a hot-meltable adhesive in which the active substance is dispersed and melted using a hot-melt process" makes the presently claimed TTS structurally distinguishable from anything found in Chen, Metman, and Loper, as none of the

references melt the active substance, and in particular, the "hot-melt deposition, extrusion and the like" of Loper employs a solution of drug and matrix material, where solvent is removed by drying (col. 8, lines 21-23). As the drug is in solution with solvent, the drug cannot be said to be "melted". Furthermore, no indication is given by Loper that "hot-melt deposition, extrusion and the like" is carried out at a temperature above the melting point of the drug, which would presumably have to be less than the boiling point of the solvent employed in Loper.

However, it is of note that the Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Further, applicant's attention is called to the examples in Neol for the teachings of hot melt process under temperature of up to 200°C.

Further, in response to applicant's argument with respect to the process recited in claim 20, it is noted that the claim does not require melting the active agent. See lines 2-3 of claim 20.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615